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Amendment and Response

Serial No.: 10/640,853

Confirmation No.: 9178

Filed: August 13, 2003

For: ACTIVE AGENT DELIVERY SYSTEMS, MEDICAL DEVICES, AND METHODS

Amendments to the Claims

This listing of claims replaces all prior versions, and listings, of claims in the above-identified application:

1. (Currently amended) A method of forming a tunable ~~An~~ active agent delivery system having a target diffusivity, the method system ~~comprising an active agent and a miscible polymer blend that controls delivery of the active agent; wherein:~~

providing a hydrophobic ~~the~~ active agent having a solubility parameter and is ~~hydrophobic and has a~~ molecular weight of no greater than about 1200 g/mol; and

combining the hydrophobic active agent with a ~~the~~ miscible polymer blend that is capable ~~of controlling delivery of the active agent and comprises:~~

a first miscible polymer having a solubility parameter, and

a second polymer selected to be miscible with the first polymer and having a solubility parameter ~~at least two miscible polymers, each with at least one solubility parameter,~~ wherein:

the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ , and the difference between at least one solubility parameter of each of ~~the at least two~~ polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ ;

at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;

the molar average solubility parameter of the blend is no greater than  $25 \text{ J}^{1/2}/\text{cm}^{3/2}$ ; and

the swellability of the blend is no greater than 10% by volume; and further wherein:

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the miscible polymer blend comprises at least one hydrophobic cellulose derivative and at least one miscible polyvinyl homopolymer or copolymer selected from the group consisting of a polyvinyl alkylate homopolymer or copolymer, a polyvinyl alkyl ether homopolymer or copolymer, a polyvinyl acetal homopolymer or copolymer, and combinations thereof; or

the miscible polymer blend comprises a polyurethane and a second miscible polymer that is not a hydrophobic cellulose ester; wherein the second miscible polymer is selected from the group consisting of a polycarbonate, a polysulfone, a polyurethane, a polyphenylene oxide, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a styrene-acrylonitrile copolymer, a poly(vinyl ester), a poly(vinyl ether), a polyacrylate, a poly(methyl acrylate), a polymethacrylate, a poly(methyl methacrylate), and combinations thereof; or

the miscible polymer blend comprises a poly(ethylene-co-(meth)acrylate) and a second miscible polymer not including poly(ethylene vinyl acetate); wherein the second miscible polymer is selected from the group consisting of a poly(vinyl alkylate) homopolymer or copolymer, a poly(vinyl alkyl ether) homopolymer or copolymer, a poly(vinyl acetal) homopolymer or copolymer, a poly(alkyl and/or aryl methacrylate) homopolymer or copolymer, a poly(alkyl and/or aryl acrylate) homopolymer or copolymer, and combinations thereof.

2. (Currently amended) The method system of claim 1 wherein:

the miscible polymer blend does not include a blend of a hydrophobic cellulose derivative and a polyurethane or a polyvinyl pyrrolidone; and/or

the miscible polymer blend does not include a blend of a polyalkyl methacrylate and a polyethylene-co-vinyl acetate.

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3. (Currently amended) The method system of claim 1 wherein the difference between at least one T<sub>g</sub> of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.
4. (Currently amended) The method system of claim 1 wherein the active agent is incorporated within the miscible polymer blend.
5. (Currently amended) The method system of claim 1 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.
6. (Currently amended) The method system of claim 1 ~~[[6]]~~ wherein the active agent is incorporated within an inner matrix.
7. (Currently amended) The method system of claim 1 wherein the miscible polymer blend includes at least one hydrophobic polymer.
8. (Currently amended) The method system of claim 1 wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ .
9. (Currently amended) The method system of claim 1 wherein the difference between at least one solubility parameter of each of at least two of the polymers is no greater than about  $3 \text{ J}^{1/2}/\text{cm}^{3/2}$ .
10. (Currently amended) A method of forming a tunable ~~An active agent delivery system having a target diffusivity, the method system comprising an active agent and a miscible polymer blend that controls delivery of the active agent, wherein:~~

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providing a hydrophilic the active agent having a solubility parameter and is hydrophilic  
~~and has~~ a molecular weight of no greater than about 1200 g/mol; and

combining the hydrophilic active agent with a the miscible polymer blend that is capable  
of controlling delivery of the active agent, and ~~comprises at least two miscible polymers,~~  
wherein:

a first miscible polymer having a solubility parameter, and

a second polymer selected to be miscible with the first polymer and having a  
solubility parameter, wherein:

the difference between the solubility parameter of the active agent and at least one  
solubility parameter of at least one of the polymers is no greater than about  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ ,  
and the difference between at least one solubility parameter of each of at least two  
polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ ;

at least one polymer has an active agent diffusivity higher than the target  
diffusivity and at least one polymer has an active agent diffusivity lower than the target  
diffusivity;

the molar average solubility parameter of the blend is greater than  $25 \text{ J}^{1/2}/\text{cm}^{3/2}$ ;  
and

the swellability of the blend is no greater than 10% by volume;  
and further wherein:

the miscible polymer blend comprises miscible polymers selected from the  
group consisting of polyacrylonitriles, cyanoacrylates, methacrylonitriles,  
hydrophilic celluloses, and combinations thereof; or

the miscible polymer blend comprises a polyurethane and at least one  
miscible hydrophilic polymer selected from the group consisting of a  
polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a  
polyvinyl pyrrolidone, a polyacrylonitrile, a polyacrylamide, a polyvinyl

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pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof; or

the miscible polymer blend comprises two hydrophobic polyurethanes as a cap coat in a reservoir system.

11. (Currently amended) The method system of claim 10 wherein the miscible polymer blend does not include both a hydrophobic cellulose derivative and a polyvinyl pyrrolidone.
12. (Currently amended) The method system of claim 10 wherein the difference between at least one Tg of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.
13. (Currently amended) The method system of claim 10 wherein the active agent is incorporated within the miscible polymer blend.
14. (Currently amended) The method system of claim 10 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.
15. (Currently amended) The method system of claim 14 wherein the active agent is incorporated within an inner matrix.
16. (Currently amended) The method system of claim 10 wherein the miscible polymer blend includes at least one hydrophilic polymer.

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17. (Currently amended) The method system of claim 10 wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ .
18. (Currently amended) The method system of claim 10 wherein the difference between at least one solubility parameter of each of at least two of the polymers is no greater than about  $3 \text{ J}^{1/2}/\text{cm}^{3/2}$ .
19. Cancelled
20. (Currently amended) A method of forming a tunable ~~An~~ active agent delivery system having a target diffusivity, the method system comprising ~~an active agent and a miscible polymer blend that controls delivery of the active agent; wherein:~~  
    providing a hydrophobic the active agent having a solubility parameter and is  
    hydrophobic and has a molecular weight of greater than about 1200 g/mol; and  
    combining the hydrophobic active agent with a the miscible polymer blend that is capable  
    of controlling delivery of the active agent and comprises at least two miscible polymers,  
    wherein:  
        a first miscible polymer having a solubility parameter, and  
        a second polymer selected to be miscible with the first polymer and having a  
    solubility parameter, wherein:  
        the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ ,  
        and the difference between at least one solubility parameter of each of at least two polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ ;  
        at least one polymer has an active agent diffusivity higher than the target

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diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;

the molar average solubility parameter of the blend is no greater than  $25 \text{ J}^{1/2}/\text{cm}^{3/2}$ ;

and

the swellability of the blend is greater than 10% by volume;

and further wherein:

the miscible polymer blend comprises at least one hydrophobic cellulose derivative and at least one miscible polymer selected from the group consisting of polyethylene, polypropylene, polyisobutylene, polystyrene, poly(vinyl chloride), poly(vinyl bromide), poly(vinylidene chloride), poly(tetrafluoroethylene), poly(chloro trifluoroethylene), poly(vinyl alcohol), poly(vinyl acetate), poly(vinyl propionate), poly(methyl acrylate), poly(ethyl acrylate), poly(propyl acrylate), poly(butyl acrylate), poly(isobutyl acrylate), poly(2,2,3,3,4,4,4-heptafluorobutyl acrylate), poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly(tert-butyl methacrylate), poly(benzyl methacrylate), poly(ethoxyethyl methacrylate), polyacrylonitrile, polymethacrylonitrile, poly(alpha-cyanomethyl acrylate), polybutadiene, polyisoprene, polychloroprene, polyformaldehyde, poly(tetramethylene oxide), poly(propylene oxide), polyepichlorohydrin, poly(ethylene sulphide), poly(styrene sulphide), poly(ethylene terephthalate), poly(8-aminocaprylic acid), poly(hexamethylenc adipamide), polyurethane hard segment (MDI + BDO), poly(bisphenyl A carbonate), cellulose acetate butyrate, phenoxy, poly(vinyl pyrrolidone), poly(vinyl pyrrolidone)-co-poly(vinyl acetate), poly(ethylene oxide), and combinations thereof.

21. (Currently amended) The method system of claim 20 wherein:  
the miscible polymer blend does not include a blend of a hydrophobic cellulose

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derivative and a polyurethane or a polyvinyl pyrrolidone; and/or

the miscible polymer blend does not include a blend of a polyalkyl methacrylate and a polyethylene-co-vinyl acetate.

22. (Currently amended) The method system of claim 20 wherein the difference between the swellabilities of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.

23. (Currently amended) The method system of claim 20 wherein the active agent is incorporated within the miscible polymer blend.

24. (Currently amended) The method system of claim 20 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.

25. (Currently amended) The method system of claim 24 wherein the active agent is incorporated within an inner matrix.

26. (Currently amended) The method system of claim 20 wherein the second polymer of the miscible polymer blend is a hydrophobic polymer.

27. (Currently amended) The method system of claim 26 wherein the miscible polymer blend includes a second polymer that is hydrophilic.

28. (Currently amended) The method system of claim 27 wherein the hydrophilic polymer is a hydrophilic polyurethane.



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29. (Currently amended) The method system of claim 20 wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ .

30. (Currently amended) The method system of claim 20 wherein the difference between at least one solubility parameter of each of at least two of the polymers is no greater than about  $3 \text{ J}^{1/2}/\text{cm}^{3/2}$ .

31. (Currently amended) The method system of claim 20 wherein the active agent is not heparin.

32. (Currently amended) A method of forming a tunable ~~An active agent delivery system~~ having a target diffusivity, the method system comprising ~~an active agent and a miscible polymer blend that controls delivery of the active agent; wherein:~~

providing a hydrophilic the active agent is hydrophilic and has having a solubility parameter and a molecular weight of greater than about 1200 g/mol; and

combining the hydrophilic active agent with a the miscible polymer blend that is capable of controlling delivery of the active agent, and comprises at least two miscible polymers, wherein:

a first miscible polymer having a solubility parameter, and

a second polymer selected to be miscible with the first polymer and having a solubility parameter, wherein:

the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ , and the difference between at least one solubility parameter of each of at least two polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ ;

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at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;

the molar average solubility parameter of the blend is greater than  $25 \text{ J}^{1/2}/\text{cm}^{3/2}$ ;

and

the swellability of the blend is greater than 10% by volume;

and further wherein:

the miscible polymer blend comprises at least one hydrophilic polymer and a second miscible polymer that is hydrophilic or hydrophobic; wherein the hydrophilic polymer is selected from the group consisting of a polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a polyvinyl pyrrolidone, a polyacrylonitrile, a polyacrylamide, a polyvinyl pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof; and the hydrophobic polymer is selected from the group consisting of a polyurethane, a polycarbonate, a polysulfone, a polyphenylene oxide, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a styrene-acrylonitrile copolymer, a polyvinyl alkylate, a polyvinyl alkyl ether, a polyvinyl acetal, a hydrophobic cellulose derivative, and combinations thereof.

33. (Currently amended) The method system of claim 32 wherein the miscible polymer blend does not include both a hydrophobic cellulose derivative and a polyvinyl pyrrolidone.

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34. (Currently amended) The method system of claim 32 wherein the difference between the swellabilities of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.

35. (Currently amended) The method system of claim 32 wherein the active agent is incorporated within the miscible polymer blend.

36. (Currently amended) The method system of claim 32 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.

37. (Currently amended) The method system of claim 36 wherein the active agent is incorporated within an inner matrix.

38. (Currently amended) The method system of claim 32 wherein the miscible polymer blend includes at least one hydrophilic polymer.

39. (Currently amended) The method system of claim 38 wherein one polymer is a hydrophilic polyurethane.

40. (Currently amended) The method system of claim 38 wherein the miscible polymer blend includes a second polymer that is hydrophobic.

41. (Currently amended) The method system of claim 32 wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ .

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42. (Currently amended) The method system of claim 32 wherein the difference between at least one solubility parameter of each of at least two of the polymers is no greater than about  $3 \text{ J}^{1/2}/\text{cm}^{3/2}$ .
43. (Currently amended) The method system of claim 32 wherein the active agent is not heparin.
44. (Currently amended) A method of making a medical device comprising; providing a medical device comprising a surface; and adhering an the active agent delivery system formed by the method of claim 1 to at least a portion of the surface.
45. (Currently amended) The method medical device of claim 44 selected from the group consisting of a stent, stent graft, anastomotic connector, lead, needle, guide wire, catheter, sensor, surgical instrument, angioplasty balloon, wound drain, shunt, tubing, urethral insert, pellet, implant, blood oxygenator, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lense.
46. (Currently amended) A method of making a medical device comprising; providing a medical device comprising a surface; and adhering an the active agent delivery system formed by the method of claim 10 to at least a portion of the surface
47. (Currently amended) The method medical device of claim 46 selected from the group consisting of a stent, stent graft, anastomotic connector, lead, needle, guide wire, catheter, sensor, surgical instrument, angioplasty balloon, wound drain, shunt, tubing, urethral insert,

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pellet, implant, blood oxygenator, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lense.

48. (Currently amended) A method of making a medical device comprising; providing a medical device comprising a surface; and adhering an the active agent delivery system formed by the method of claim 20 to at least a portion of the surface.

49. (Currently amended) The method ~~medical device~~ of claim 48 selected from the group consisting of a stent, stent graft, anastomotic connector, lead, needle, guide wire, catheter, sensor, surgical instrument, angioplasty balloon, wound drain, shunt, tubing, urethral insert, pellet, implant, blood oxygenator, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lense.

50. (Currently amended) A method of making a medical device comprising; providing a medical device comprising a surface; and adhering an the active agent delivery system formed by the method of claim 32 to at least a portion of the surface.

51. (Currently amended) The method ~~medical device~~ of claim 50 selected from the group consisting of a stent, stent graft, anastomotic connector, lead, needle, guide wire, catheter, sensor, surgical instrument, angioplasty balloon, wound drain, shunt, tubing, urethral insert, pellet, implant, blood oxygenator, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lense.

52. (Currently amended) A method of making a stent comprising; providing a stent comprising a surface; and

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adhering an the active agent delivery system formed by the method of claim 1 to at least a portion of the surface.

53. (Currently amended) A method of making a stent comprising;  
providing a stent comprising a surface; and  
adhering an the active agent delivery system formed by the method of claim 10 to at least a portion of the surface.

54. (Currently amended) A method of making a stent comprising;  
providing a stent comprising a surface; and  
adhering an the active agent delivery system formed by the method of claim 20 to at least a portion of the surface.

55. (Currently amended) A method of making a stent comprising;  
providing a stent comprising a surface; and  
adhering an the active agent delivery system formed by the method of claim 32 to at least a portion of the surface.

56. (Currently amended) A method of designing an active agent delivery system for delivering an active agent over a preselected dissolution time (t) through a preselected critical dimension (x) of a miscible polymer blend that controls delivery of the active agent, the method comprising:  
providing an active agent having a solubility parameter and a molecular weight no greater than about 1200 g/mol;  
providing a first miscible polymer having a solubility parameter;  
selecting a second polymer to be miscible with the first polymer and having a solubility parameter at least two miscible polymers, wherein:

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the difference between the solubility parameter of the active agent and at least one solubility parameter of each of the polymers is no greater than about  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ , and the difference between at least one solubility parameter of each of the ~~at least two~~ polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ ;

the difference between at least one Tg of each of the ~~at least two~~ polymers is sufficient to include the target diffusivity; combining the ~~at least two~~ polymers to form a miscible polymer blend; and

combining the miscible polymer blend with the active agent to form an active agent delivery system having the preselected dissolution time through a preselected critical dimension of the miscible polymer blend;

wherein:

the miscible polymer blend comprises at least one hydrophobic cellulose derivative and at least one miscible polyvinyl homopolymer or copolymer selected from the group consisting of a polyvinyl alkylate homopolymer or copolymer, a polyvinyl alkyl ether homopolymer or copolymer, a polyvinyl acetal homopolymer or copolymer, and combinations thereof; or

the miscible polymer blend comprises a polyurethane and a second miscible polymer that is not a hydrophobic cellulose ester; wherein the second miscible polymer is selected from the group consisting of a polycarbonate, a polysulfone, a polyurethane, a polyphenylene oxide, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a styrene-acrylonitrile copolymer, a poly(vinyl ester), a poly(vinyl ether), a polyacrylate, a poly(methyl acrylate), a polymethacrylate, a poly(methyl methacrylate), and combinations thereof; or

the miscible polymer blend comprises a poly(ethylene-co-(meth)acrylate) and a second miscible polymer not including poly(ethylene vinyl acetate); wherein the second miscible polymer is selected from the group consisting of a poly(vinyl alkylate) homopolymer or copolymer, a poly(vinyl alkyl ether) homopolymer or copolymer, a poly(vinyl acetal) homopolymer or copolymer, a poly(alkyl and/or aryl methacrylate) homopolymer or copolymer, a poly(alkyl and/or aryl acrylate) homopolymer or copolymer, and combinations thereof; or

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the miscible polymer blend comprises miscible polymers selected from the group consisting of polyacrylonitriles, cyanoacrylates, methacrylonitriles, hydrophilic celluloses, and combinations thereof; or

the miscible polymer blend comprises a polyurethane and at least one miscible hydrophilic polymer selected from the group consisting of a polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a polyvinyl pyrrolidone, a polyacrylonitrile, a polyacrylamide, a polyvinyl pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof; or

the miscible polymer blend comprises two hydrophobic polyurethanes as a cap coat in a reservoir system.

57. (Original) The method of claim 56 wherein the active agent is incorporated within the miscible polymer blend.
58. (Original) The method of claim 56 wherein miscible polymer blend initially provides a barrier for permeation of the active agent.
59. (Original) The method of claim 56 wherein the active agent is incorporated within an inner matrix.
60. (Original) The method of claim 56 wherein the active agent is hydrophobic.
61. (Previously Presented) The method of claim 56 wherein the active agent is hydrophilic.



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62. (Currently amended) The method of claim 56 ~~[[48]]~~ wherein:

the miscible polymer blend does not include a blend of a hydrophobic cellulose derivative and a polyurethane or a polyvinyl pyrrolidone; and/or

the miscible polymer blend does not include a blend of a polyalkyl methacrylate and a polyethylene-co-vinyl acetate.

63. (Currently amended) A method of designing an active agent delivery system for delivering an active agent over a preselected dissolution time (t) through a preselected critical dimension (x) of a miscible polymer blend that controls delivery of the active agent, the method comprising:

providing an active agent having a solubility parameter and a molecular weight greater than about 1200 g/mol;

providing a first miscible polymer having a solubility parameter;

selecting a second polymer to be miscible with the first polymer and having a solubility parameter at least two miscible polymers, wherein:

the difference between the solubility parameter of the active agent and at least one solubility parameter of each of the polymers is no greater than about  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ , and the difference between at least one solubility parameter of each of the ~~at least two~~ polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ ;

the difference between the swellabilities of the ~~at least two~~ polymers is sufficient to include the target diffusivity;

combining the ~~at least two~~ polymers to form a miscible polymer blend; and

combining the miscible polymer blend with the active agent to form an active agent delivery system having the preselected dissolution time through a preselected critical dimension of the miscible polymer blend;

wherein:

the miscible polymer blend comprises at least one hydrophobic cellulose derivative and a second polymer selected from the group consisting of polyethylene,

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polypropylene, polyisobutylene, polystyrene, poly(vinyl chloride), poly(vinyl bromide), poly(vinylidene chloride), poly(tetrafluoroethylene), poly(chloro trifluoroethylene), poly(vinyl alcohol), poly(vinyl acetate), poly(vinyl propionate), poly(methyl acrylate), poly(ethyl acrylate), poly(propyl acrylate), poly(butyl acrylate), poly(isobutyl acrylate), poly(2,2,3,3,4,4,4-heptafluorobutyl acrylate), poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly(tert-butyl methacrylate), poly(benzyl methacrylate), poly(ethoxyethyl methacrylate), polyacrylonitrile, polymethacrylonitrile, poly(alpha-cyanomethyl acrylate), polybutadiene, polyisoprene, polychloroprene, polyformaldehyde, poly(tetramethylene oxide), poly(propylene oxide), polyepichlorohydrin, poly(ethylene sulphide), poly(styrene sulphide), poly(ethylene terephthalate), poly(8-aminocaprylic acid), poly(hexamethylene adipamide), polyurethane hard segment (MDI + BDO), poly(bisphenyl A carbonate), cellulose acetate butyrate, phenoxy, poly(vinyl pyrrolidone), poly(vinyl pyrrolidone)-co-poly(vinyl acetate), poly(ethylene oxide), and combinations thereof; or

the miscible polymer blend comprises at least one hydrophilic polymer and a second miscible polymer that is hydrophilic or hydrophobic; wherein the hydrophilic polymer is selected from the group consisting of a polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a polyvinyl pyrrolidone, a polyacrylonitrile, a polyacrylamide, a polyvinyl pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof; and the hydrophobic polymer is selected from the group consisting of a polyurethane, a polycarbonate, a polysulfone, a polyphenylene oxide, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a

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styrene-acrylonitrile copolymer, a polyvinyl alkylate, a polyvinyl alkyl ether, a polyvinyl acetal, a hydrophobic cellulose derivative, and combinations thereof.

64. (Original) The method of claim 63 wherein the active agent is incorporated within the miscible polymer blend.

65. (Original) The method of claim 63 wherein miscible polymer blend initially provides a barrier for permeation of the active agent.

66. (Original) The method of claim 63 wherein the active agent is incorporated within an inner matrix.

67. (Original) The method of claim 63 wherein the active agent is hydrophobic.

68. (Original) The method of claim 63 wherein the active agent is hydrophilic.

69. (Original) The method of claim 63 wherein the active agent is not heparin.

70. (Original) The method of claim 63 wherein:

the miscible polymer blend does not include a blend of a hydrophobic cellulose derivative and a polyurethane or a polyvinyl pyrrolidone; and/or

the miscible polymer blend does not include a blend of a polyalkyl methacrylate and a polyethylene-co-vinyl acetate.

71. (Currently amended) A method for delivering an active agent to a subject, the method comprising:

providing the active agent delivery system of formed according to the method claim 1; and

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contacting the active agent delivery system with a bodily fluid, organ, or tissue of a subject.

72. (Currently amended) A method for delivering an active agent to a subject, the method comprising:

providing the active agent delivery system formed according to the method of claim 10; and

contacting the active agent delivery system with a bodily fluid, organ, or tissue of a subject.

73. (Currently amended) A method for delivering an active agent to a subject, the method comprising:

providing the active agent delivery system formed according to the method of claim 20; and

contacting the active agent delivery system with a bodily fluid, organ, or tissue of a subject.

74. (Currently amended) A method for delivering an active agent to a subject, the method comprising:

providing the active agent delivery system formed according to the method of claim 32; and

contacting the active agent delivery system with a bodily fluid, organ, or tissue of a subject.

75. (Currently amended) A method for tuning the delivery of an active agent to a subject, the method comprising:

providing an active agent delivery system comprising an active agent having a molecular weight no greater than about 1200 g/mol and a miscible polymer blend, comprising:

providing a first miscible polymer having a solubility parameter;

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selecting a second polymer to be miscible with the first polymer and having a solubility parameter;

combining the first polymer and the second polymer at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent; wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of each of the polymers is no greater than about  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ , and the difference between at least one solubility parameter of each of the ~~at least two~~ polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ ; and

combining the miscible polymers and an active agent in amounts sufficient to form the active agent delivery system comprising a miscible polymer blend capable of delivering an active agent at a predetermined release rate; and

contacting the active agent delivery system with a bodily fluid, organ, or tissue of a subject to deliver the active agent at the predetermined release rate;

wherein:

the miscible polymer blend comprises at least one hydrophobic cellulose derivative and at least one miscible polyvinyl homopolymer or copolymer selected from the group consisting of a polyvinyl alkylate homopolymer or copolymer, a polyvinyl alkyl ether homopolymer or copolymer, a polyvinyl acetal homopolymer or copolymer, and combinations thereof; or

the miscible polymer blend comprises a polyurethane and a second miscible polymer that is not a hydrophobic cellulose ester; wherein the second miscible polymer is selected from the group consisting of a polycarbonate, a polysulfone, a polyurethane, a polyphenylene oxide, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a styrene-acrylonitrile copolymer, a poly(vinyl ester), a poly(vinyl ether), a polyacrylate, a poly(methyl acrylate), a polymethacrylate, a poly(methyl methacrylate), and combinations thereof; or

the miscible polymer blend comprises a poly(ethylene-co-(meth)acrylate) and a second miscible polymer not including poly(ethylene vinyl acetate); wherein the second miscible polymer is selected from the group consisting of a poly(vinyl alkylate) homopolymer or copolymer, a poly(vinyl alkyl ether) homopolymer or copolymer, a poly(vinyl acetal)

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homopolymer or copolymer, a poly(alkyl and/or aryl methacrylate) homopolymer or copolymer, a poly(alkyl and/or aryl acrylate) homopolymer or copolymer, and combinations thereof; or

the miscible polymer blend comprises miscible polymers selected from the group consisting of polyacrylonitriles, cyanoacrylates, methacrylonitriles, hydrophilic cellulose, and combinations thereof; or

the miscible polymer blend comprises a polyurethane and at least one miscible hydrophilic polymer selected from the group consisting of a polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a polyvinyl pyrrolidone, a polyacrylonitrile, a polyacrylamide, a polyvinyl pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof; or

the miscible polymer blend comprises two hydrophobic polyurethanes as a cap coat in a reservoir system.

76. (Currently amended) A method of forming a tunable active agent delivery system comprising:

providing a first miscible polymer having a solubility parameter;

selecting a second polymer to be miscible with the first polymer ~~at least two miscible polymers~~ to form a miscible polymer blend that controls the delivery of the active agent having a molecular weight of no greater than about 1200 g/mol; wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of each of the polymers is no greater than about  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ , and the difference between at least one solubility parameter of each of the ~~at least two~~ polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ ; and

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combining the ~~at least two~~ miscible polymers in amounts sufficient to form a miscible polymer blend capable of delivering the active agent at a predetermined release rate; and

combining at least one active agent with the miscible polymer blend such that the miscible polymer blend controls the delivery of the active agent at the predetermined release rate;

wherein:

the miscible polymer blend comprises at least one hydrophobic cellulose derivative and at least one miscible polyvinyl homopolymer or copolymer selected from the group consisting of a polyvinyl alkylate homopolymer or copolymer, a polyvinyl alkyl ether homopolymer or copolymer, a polyvinyl acetal homopolymer or copolymer, and combinations thereof; or

the miscible polymer blend comprises a polyurethane and a second miscible polymer that is not a hydrophobic cellulose ester; wherein the second miscible polymer is selected from the group consisting of a polycarbonate, a polysulfone, a polyurethane, a polyphenylene oxide, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a styrene-acrylonitrile copolymer, a poly(vinyl ester), a poly(vinyl ether), a polyacrylate, a poly(methyl acrylate), a polymethacrylate, a poly(methyl methacrylate), and combinations thereof; or

the miscible polymer blend comprises a poly(ethylene-co-(meth)acrylate) and a second miscible polymer not including poly(ethylene vinyl acetate); wherein the second miscible polymer is selected from the group consisting of a poly(vinyl alkylate) homopolymer or copolymer, a poly(vinyl alkyl ether) homopolymer or copolymer, a poly(vinyl acetal) homopolymer or copolymer, a poly(alkyl and/or aryl methacrylate) homopolymer or copolymer, a poly(alkyl and/or aryl acrylate) homopolymer or copolymer, and combinations thereof; or

the miscible polymer blend comprises miscible polymers selected from the group consisting of polyacrylonitriles, cyanoacrylates, methacrylonitriles, hydrophilic celluloses, and combinations thereof; or

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the miscible polymer blend comprises a polyurethane and at least one miscible hydrophilic polymer selected from the group consisting of a polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a polyvinyl pyrrolidone, a polyacrylonitrile, a polyacrylamide, a polyvinyl pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof; or

the miscible polymer blend comprises two hydrophobic polyurethanes as a cap coat in a reservoir system.

77. (Currently amended) A method of forming a tunable active agent delivery system comprising:

providing a first miscible polymer having a solubility parameter;

selecting a second polymer to be miscible with the first polymer ~~at least two miscible polymers~~ to form a miscible polymer blend that controls the delivery of the active agent having a molecular weight of greater than about 1200 g/mol; wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of each of the polymers is no greater than about  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ , and the difference between at least one solubility parameter of each of the ~~at least two~~ polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ ; and

combining the first polymer and the second polymer ~~at least two miscible polymers~~ in amounts sufficient to form a miscible polymer blend capable of delivering the active agent at a predetermined release rate; and

combining at least one active agent with the miscible polymer blend such that the miscible polymer blend controls the delivery of the active agent at the predetermined release rate;



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wherein:

the miscible polymer blend comprises at least one hydrophobic cellulose derivative and at least one miscible polymer selected from the group consisting of polyethylene, polypropylene, polyisobutylene, polystyrene, poly(vinyl chloride), poly(vinyl bromide), poly(vinylidene chloride), poly(tetrafluoroethylene), poly(chloro trifluoroethylene), poly(vinyl alcohol), poly(vinyl acetate), poly(vinyl propionate), poly(methyl acrylate), poly(ethyl acrylate), poly(propyl acrylate), poly(butyl acrylate), poly(isobutyl acrylate), poly(2,2,3,3,4,4,4-heptafluorobutyl acrylate), poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly(tert-butyl methacrylate), poly(benzyl methacrylate), poly(ethoxyethyl methacrylate), polyacrylonitrile, polymethacrylonitrile, poly(alpha-cyanomethyl acrylate), polybutadiene, polyisoprene, polychloroprene, polyformaldehyde, poly(tetramethylene oxide), poly(propylene oxide), polyepichlorohydrin, poly(ethylene sulphide), poly(styrene sulphide), poly(ethylene terephthalate), poly(8-aminocaprylic acid), poly(hexamethylene adipamide), polyurethane hard segment (MDI + BDO), poly(bisphenyl A carbonate), cellulose acetate butyrate, phenoxy, poly(vinyl pyrrolidone), poly(vinyl pyrrolidone)-co-poly(vinyl acetate), poly(ethylene oxide), and combinations thereof; or

the miscible polymer blend comprises at least one hydrophilic polymer and a second miscible polymer that is hydrophilic or hydrophobic; wherein the hydrophilic polymer is selected from the group consisting of a polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a polyvinyl pyrrolidone, a polyacrylonitrile, a polyacrylamide, a polyvinyl pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof; and the hydrophobic polymer is selected from the group consisting of a polyurethane, a polycarbonate, a polysulfone, a polyphenylene

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osied, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a styrene-acrylonitrile copolymer, a polyvinyl alkylate, a polyvinyl alkyl ether, a polyvinyl acetal, a hydrophobic cellulose derivative, and combinations thereof.

78. (Currently amended) A method for tuning the delivery of an active agent to a subject, the method comprising:

providing an active agent delivery system comprising an active agent having a molecular weight greater than about 1200 g/mol and a miscible polymer blend, comprising:

providing a first miscible polymer having a solubility parameter;

selecting at least two miscible polymers a second polymer to be miscible with the first polymer and having solubility parameter;

combining the first polymer and the second polymer to form a miscible polymer blend that controls the delivery of the active agent; wherein the difference between the solubility parameter of the active agent and at least one solubility parameter of each of the polymers is no greater than about  $10 \text{ J}^{1/2}/\text{cm}^{3/2}$ , and the difference between at least one solubility parameter of each of the at least two polymers is no greater than about  $5 \text{ J}^{1/2}/\text{cm}^{3/2}$ ; and

combining the miscible polymers and an active agent in amounts sufficient to form the active agent delivery system comprising a miscible polymer blend capable of delivering an active agent at a predetermined release rate; and

contacting the active agent delivery system with a bodily fluid, organ, or tissue of a subject to deliver the active agent at the predetermined release rate;

wherein:

the miscible polymer blend comprises at least one hydrophobic cellulose derivative and at least one miscible polymer selected from the group consisting of polyethylene, polypropylene, polyisobutylene, polystyrene, poly(vinyl chloride), poly(vinyl bromide), poly(vinylidene chloride), poly(tetrafluoroethylene), poly(chloro trifluoroethylene), poly(vinyl alcohol), poly(vinyl acetate), poly(vinyl propionate), poly(methyl acrylate), poly(ethyl acrylate), poly(propyl acrylate), poly(butyl acrylate),

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poly(isobutyl acrylate), poly(2,2,3,3,4,4,4-heptafluorobutyl acrylate), poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly(tert-butyl methacrylate), poly(benzyl methacrylate), poly(ethoxyethyl methacrylate), polyacrylonitrile, polymethacrylonitrile, poly(alpha-cyanomethyl acrylate), polybutadiene, polyisoprene, polychloroprene, polyformaldehyde, poly(tetramethylene oxide), poly(propylene oxide), polyepichlorohydrin, poly(ethylene sulphide), poly(styrene sulphide), poly(ethylene terephthalate), poly(8-aminocaprylic acid), poly(hexamethylene adipamide), polyurethane hard segment (MDI + BDO), poly(bisphenyl A carbonate), cellulose acetate butyrate, phenoxy, poly(vinyl pyrrolidone), poly(vinyl pyrrolidone)-co-poly(vinyl acetate), poly(ethylene oxide), and combinations thereof; or

the miscible polymer blend comprises at least one hydrophilic polymer and a second miscible polymer that is hydrophilic or hydrophobic; wherein the hydrophilic polymer is selected from the group consisting of a polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a polyvinyl pyrrolidone, a polyacrylonitrile, a polyacrylamide, a polyvinyl pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof; and the hydrophobic polymer is selected from the group consisting of a polyurethane, a polycarbonate, a polysulfone, a polyphenylene oxide, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a styrene-acrylonitrile copolymer, a polyvinyl alkylate, a polyvinyl alkyl ether, a polyvinyl acetal, a hydrophobic cellulose derivative, and combinations thereof.